UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

POP VAPOR CO., LLC, 3017 Boiling Way NE Atlanta, GA 30305, Plaintiff, v. U.S. FOOD AND DRUG ADMINISTRATION, ROBERT M. CALIFF, M.D., Commissioner of Food and Drugs, 10903 New Hampshire Avenue, Silver Spring, MD 20903, and U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, XAVIER BECERRA, J.D., Secretary of Health and Human Services, 200 Independence Avenue, SW, Washington DC 20201, Defendants.	)	Case No. _____

COMPLAINT

Plaintiff Pop Vapor Co., LLC ("Plaintiff") brings this Complaint for Declaratory and Injunctive Relief against Defendants – the United States Food and Drug Administration ("FDA"), Robert M. Califf, M.D. (in his official capacity as the Commissioner of Food and Drugs), the United States Department of Health and

Human Services ("HHS"), and Xavier Becerra, J.D. (in his official capacity as Secretary of Health and Human Services). In support thereof, Plaintiff states as follows:

INTRODUCTION

1. This action is an Administrative Procedure Act challenge to FDA's refusal to accept Plaintiff's Premarket Tobacco Applications for various electronic nicotine delivery systems – also referred to as "ENDS," "electronic cigarettes," and "e-cigarettes."[1]

2. As is discussed in more detail below, FDA refused to accept Plaintiff's applications for further review on the grounds that the applications did not set forth

[1] Unlike traditional combustible cigarettes, ENDS products do not contain tobacco leaf that is burned to create smoke that the user inhales. Instead, ENDS products use an "e-liquid" that usually contains nicotine (either derived from tobacco or manufactured synthetically) and other ingredients. The liquid is heated to create an aerosol that the user inhales. FDA has stated that "ENDS are generally likely to have fewer and lower concentrations of harmful and potentially harmful constituents (HPHCs) than combustible cigarettes, and biomarker studies demonstrate significantly lower exposure to HPHCs among current exclusive ENDS users than current smokers." *Wages and White Lion Investments L.L.C. v. FDA*, No. 21-60766, Joint Appendix at 92 (5th Cir. Jan. 14, 2022); *see also Breeze Smoke, LLC v. FDA*, 18 F.4th 499, 505 (6th Cir. 2021) (stating FDA has acknowledged "that ENDS products may provide a beneficial alternative to combustible cigarettes because they deliver nicotine without also bombarding the user's lungs with the toxins found in cigarettes").

the "length" of Plaintiff's electronic cigarettes. However, Plaintiff's applications did include that information.

3. FDA's wrongful refusal to accept the applications injures Plaintiff in that it (1) deprives Plaintiff of its right to further review of the applications; and (2) subjects Plaintiff to possible FDA enforcement action for continued marketing of its products.

4. Plaintiff asks this Court to, among other things, (1) declare that its applications complied with FDA's regulations for the content of Premarket Tobacco Applications; (2) set aside FDA's refusal to accept the applications; and (3) order FDA to accept Plaintiff's applications for further review.

PARTIES

5. Plaintiff Pop Vapor Co., LLC is a Georgia limited liability company with its principal office at 3017 Boiling Way, Atlanta, GA 30305.

6. Defendant United States Food and Drug Administration is an executive branch agency of the federal government and is headquartered at 10903 New Hampshire Avenue, Silver Spring, MD 20903.

7. Defendant Robert M. Califf, MD (sued here only in his official capacity), is the Commissioner of Food and Drugs and an officer of the United States. His office is at 10903 New Hampshire Avenue, Silver Spring, MD 20903.

8. Defendant United States Department of Health and Human Services is an executive branch agency of the federal government and is headquartered at 200 Independence Avenue, S.W., Washington, DC 20201.

9. Defendant Xavier Bacerra, JD, (sued here only in his official capacity) is the Secretary of Health and Human Services and an officer of the United States. His office is at 200 Independence Avenue, S.W., Washington, DC 20201.

10. FDA is an operating division of HHS. The Commissioner of Food and Drugs reports to the Secretary of Health and Human Services.

JURISDICTION AND VENUE

11. This action arises under and asserts violations of the Administrative Procedure Act ("APA"), 5 U.S.C. § 551 *et seq.*, and the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq*. The Court therefore has subject-matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1346, and 1361.

12. The Declaratory Judgment Act authorizes the Court to grant Plaintiff's request for declaratory relief. 28 U.S.C. §§ 2201-2202.

13. Venue is proper in this district pursuant to 28 U.S.C. § 1391 (b) and (e) and 5 U.S.C. § 703.

RELEVANT LAW AND FACTS

A. The FDCA's Premarket Tobacco Application Requirement for New Tobacco Products.

14. Under the FDCA, as amended by the Family Smoking Prevention and Tobacco Control Act of 2009, anyone wishing to market a "new tobacco product" in interstate commerce must file a Premarket Tobacco Application ("PMTA") with FDA and receive a Marketing Granted Order from FDA. *See* 21 U.S.C. § 387j.

15. The FDCA requires FDA to issue a Marketing Granted Order if the PMTA demonstrates, among other things, that permitting marketing of the new tobacco product "would be appropriate for the protection of the public health." 21 U.S.C. § 387j(c)(2)(A).

16. A "new tobacco product" is one "that was not commercially marketed in the United States as of February 15, 2007." 21 U.S.C. § 387j(a)(1)(A).

17. The PMTA requirements originally extended only to cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. 21 U.S.C. § 387a(b).

18. The PMTA requirements were extended to ENDS products containing nicotine derived from tobacco in August 2016, *see* 81 Fed. Reg. 28974 (May 10, 2016); and were extended to ENDS products "containing nicotine from any source" (*i.e.*, synthetic nicotine) in April 2022, *see* Pub. L. 117-103, § 111(a)(1); 21 U.S.C. § 321(rr)(1).

19. FDA is required to issue a decision on a PMTA no later than 180 days after receipt of the PMTA. 21 U.S.C. § 387j(c)(1)(A).

20. FDA regulations set forth the required content and format of PMTAs. *See* 21 C.F.R. §§ 1105.10, 1114.7.

21. FDA regulations provide for the following three stages of PMTA review:

a. Acceptance review. When an applicant submits a PMTA to FDA, the agency conducts an initial review "to determine whether the PMTA may be accepted for further review." 21 C.F.R. § 1114.27(a). FDA must "accept" a PMTA for further review if the application complies with the 21 C.F.R. section 1105.10 and 1114.7 content and format requirements. 21 C.F.R. § 1114.27(a). If FDA does not "accept" a PMTA, it will issue a "Refuse to Accept" Letter and "close" the application. 21 C.F.R. §§ 1114.27(a), 1114.29(a), (b).

b. Filing review. If FDA "accepts" a PMTA, it then makes "a threshold determination of whether the application contains sufficient information to permit a substantive review" (also called "application review"). 21 C.F.R. § 1114.27(b). If the PMTA contains sufficient

information for "substantive review," FDA "files" the application. 21 C.F.R. § 1114.27(b)(2).

c. Substantive review. If FDA "files" the PMTA, it will then conduct a "substantive review" of the application and "act on the application" within 180 days of the date of filing. 21 C.F.R. § 1114.27(c)(1)-(2).

22. There have been instances in which FDA said that a PMTA did not include certain required information but later admitted that the PMTA did include that information. *See, e.g.*, *Turning Point Brands, Inc. v. FDA*, Case No. 21-3855, Doc. 19 (6th Cir. Oct. 8, 2021) (FDA rescinded denial of PMTA because the application included information the agency originally said was missing).

B. FDA's Exercise of Enforcement Discretion for ENDS Products with Timely-Filed PMTAs Undergoing any Stage of Review.

23. The distribution of an FDA-regulated product without the required FDA marketing authorization may result in an FDA enforcement action.

24. FDA enforcement actions with respect to tobacco products include, among other things:

a. Administrative civil money penalty proceedings that may result in penalties of up to $19,192 for each violation, not to exceed $1,279,448 for all violations adjudicated in a single proceeding. *See* 21 U.S.C. § 333(f)(9)(A); 21 C.F.R. § 17.2; 45 C.F.R. § 102.3; *see, e.g., FDA Center for*

Tobacco Products v. RTP Vapors, LLC, Case No. T-23-2137, Doc. No. 1 (HHS Departmental Appeals Bd. May 10, 2023) (complaint seeking civil money penalty of $19,192 based on allegation that defendant marketed ENDS products without FDA Marketing Granted Orders); and

b. Injunction proceedings in a United States district court that may result in a permanent injunction prohibiting defendant from marketing its products. *See* 21 U.S.C. § 332(a); *see, e.g.*, *United States v. Vapor Craft, LLC*, Case No. 22-cv-00160-CDL, Doc. No. 1 (M.D. Ga. Oct. 18, 2022) (complaint for permanent injunction based on allegation that defendant marketed ENDS products without FDA Marketing Granted Orders).

25. However, FDA often exercises "enforcement discretion" – *i.e.*, refrains from bringing an enforcement action – for products that do not have FDA marketing authorization. *See, e.g.*, FDA Compliance Policy Guide § 440.100 (describing how FDA "intend[s] to exercise [its] enforcement discretion with regard to drugs marketed in the United States that do not have required FDA approval for marketing").

26. Because many ENDS products were legally on the market before they became subject to the FDCA's PMTA requirements, FDA's policy has been to exercise enforcement discretion for ENDS products with timely-filed PMTAs so

long as those PMTAs are undergoing any stage of FDA review (be it acceptance review, filing review, or substantive review). *See generally, Vapor Tech. Ass'n v. FDA*, 977 F.3d 496 (6th Cir. 2020) (discussing FDA enforcement discretion policy for ENDS containing nicotine derived from tobacco).

27. Indeed, based on a review of an FDA's website that lists all civil money penalty and civil injunction actions brought against ENDS manufacturers, it appears that FDA has never initiated a civil money penalty action or civil injunction action against an ENDS manufacturer relating to a product for which there was a timely-filed PMTA undergoing any stage of FDA review.[2]

C. FDA's Refusal to Accept Plaintiff's Timely-Filed PMTAs.

28. On May 13, 2022, Plaintiff, through its scientific consultants, submitted bundled PMTAs for various tobacco-flavored and non-tobacco-flavored electronic cigarettes containing synthetic nicotine.[3]

29. Plaintiff submitted various amendments to the PMTAs in July and October of 2022.

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[2] *See* https://www.fda.gov/tobacco-products/compliance-enforcement-training/advisory-and-enforcement-actions-against-industry-unauthorized-tobacco-products (last accessed August 1, 2023).

[3] A "bundled" PMTA is "a single premarket submission for multiple products." 86 Fed. Reg. 55300, 55317.

30. The products included in the PMTAs that are at issue in this Complaint are identified by their Submission Tracking Number ("STN") and Product Name in the margin below.[4]

31. Because Plaintiff submitted the PMTAs by May 14, 2022 (one month after the FDCA was amended to cover synthetic nicotine), its ENDS products were not immediately subject to an FDA enforcement action. *See* Pub. L. 117-103, § 111(d).

[4] The PMTAs that are the subject of this Complaint are: PM0005527.PD4 (POP-FLEX Virginia Tobacco); PM0005527.PD5 (POP-FLEX Menthol); PM0005527.PD6 (POP-FLEX Classic); PM0005527.PD7 (POP-BAR Virginia Tobacco); PM0005527.PD8 (POP-BAR Menthol); PM0005527.PD9 (POP-BAR Classic); PM0005527.PD22 (POP-EXTRA Virginia Tobacco); PM0005527.PD23 (POP-EXTRA Menthol); PM0005569.PD11 (POP-FLEX, Strawberry Banana Ice); PM0005569.PD12 (POP-FLEX, Strawberry Bubblegum Ice); PM0005569.PD13 (POP-FLEX, Rainbow Candy); PM0005569.PD14 (POP-FLEX, Blueberry Mint); PM0005569.PD15 (POP-FLEX, Blue Raz); PM0005569.PD16 (POP-FLEX, Cool Mint); PM0005569.PD17 (POP-FLEX, Watermelon Apple); PM0005569.PD18 (POP-BAR, Dewberry); PM0005569.PD19 (POP-BAR, Bubblegum); PM0005569.PD20 (POP-FLEX, Watermelon Mint); PM0005569.PD21 (POP-FLEX, Peachy Rings); PM0005569.PD22 (POP-FLEX, Tropical Punch); PM0005569.PD23 (POP-BAR, Green Apple); PM0005569.PD24 (POP-BAR, Peach Gelato); PM0005569.PD25 (POP-BAR, Blue Raz Slushy); PM0005569.PD26 (POP-BAR, Cool Mint); PM0005569.PD27 (POP-Bar, Red Bang); PM0005569.PD28 (POP-BAR, Lush Ice); PM0005569.PD29 (POP-BAR, Strawberry Watermelon); PM0005569.PD30 (POP-BAR, Banana Ice). Other PMTAs included in the bundled PMTAs (referenced in paragraphs 2 and 3 of the FDA's Refuse to Accept Letter) are not at issue in this Complaint.

32. Plaintiff's PMTAs complied with FDA's regulations regarding the required content and format for PMTAs. 21 C.F.R. §§ 1105.10, 1114.7.

33. In accordance with 21 C.F.R. § 1114.7(c)(3)(iii), Table 1 to ¶ (c)(3)(iii), Plaintiff's PMTAs set forth, among other things, the "length" of each e-cigarette. Specifically, the PMTAs included amended FDA Forms 4057b that listed each e-cigarette's measurements in a column titled "Diameter Numeric Value," with the largest number in the measurement representing the product's length. For example, the amended Form 4057b stated that the POP-FLEX products were 79.5mm x 47mm x 25.6mm. The products' measurements were also provided in other portions of the PMTAs. *See* Module 2.3.1 Product Design Summary Revision 1.0 at 16, 18, 19.

34. Approximately six months after Plaintiff submitted the PMTAs, FDA issued a Refuse to Accept Letter for those PMTAs because, according to FDA, Plaintiff's "FDA Form 4057b … did not include the length [of the] products." *See* Ex. A, Refuse to Accept Letter, at 1-2 (Nov. 21, 2022).

35. At no time did FDA send Plaintiff a deficiency letter asking Plaintiff to submit information that was allegedly missing from the PMTAs. *See R.J. Reynolds Vapor Co. v. FDA*, 64 F.4th 182, 188 (5th Cir. 2023) (noting that FDA sent a PMTA applicant a deficiency letter requesting that the applicant provide additional information in support of its applications).

36. FDA's Refuse to Accept Letter stated that the agency's decision meant that FDA would not conduct further review of the PMTAs. Ex. A at 1.

37. FDA's Refuse to Accept Letter also warned: "You cannot introduce or deliver for introduction these products into interstate commerce in the United States. Doing so is a prohibited act under [21 U.S.C. § 331(a)], the violation of which could result in enforcement action by FDA." *Id.* at 3.

38. FDA's Refuse to Accept Letter said that Plaintiff could "submit new PMTAs for these products" with the allegedly missing information. *Id.* at 3. However, it is Plaintiff's understanding that FDA would consider such "new PMTAs" to be submitted after May 14, 2022, and that the products would therefore not be eligible for FDA's policy of enforcement discretion for products with timely-filed PMTAs undergoing any stage of FDA review.

D. Plaintiff's Petition for Review at the Eleventh Circuit.

39. The FDCA provides that United States Courts of Appeal have jurisdiction to review "a denial" of a PMTA. 21 U.S.C. § 387*l*(a)(1)(B).

40. Petitions for review must be filed within 30 days after the denial of a PMTA. *Id.*

41. On December 16, 2022, Plaintiff filed a petition for review of FDA's Refuse to Accept Letter at the United States Court of Appeals for the Eleventh Circuit. *See Pop Vapor Co. LLC v. FDA*, Case No. 22-14144-B (11th Cir.).

42. On May 11, 2023, the Eleventh Circuit dismissed the petition for lack of subject matter jurisdiction on the grounds that a Refuse to Accept Letter is not a "denial" of a PMTA under 21 U.S.C. § 387*l*(a)(1)(B). *See Pop Vapor Co. LLC v. FDA*, Case No. 22-14144-B, Doc. 13-2 (11th Cir. May 11, 2023).

43. The Eleventh Circuit's order does address whether a Refuse to Accept Letter is "final agency action" reviewable by a district court under the Administrative Procedure Act. *See* 5 U.S.C. § 704.

COUNT I
Administrative Procedure Act

44. Plaintiff repeats each of the preceding paragraphs as if fully set forth herein.

45. Under the APA, a "final agency action for which there is no other adequate remedy in a court" is "subject to judicial review." 5 U.S.C. § 704.

46. The APA requires a court to "hold unlawful and set aside" final agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law." 5 U.S.C. § 706(2).

47. A court's APA "review of agency action is limited to the grounds that the agency invoked when it took the action." *Dep't of Homeland Sec. v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1907 (2020) (cleaned up).

48. FDA's Refusal to Accept Letter for the PMTAs at issue is subject to judicial review under the APA because it is a "final agency action for which there is no other adequate remedy in a court." 5 U.S.C. § 704; *see, e.g.*, *Braeburn v. FDA*, 389 F. Supp. 3d 1 (D.D.C. 2019) (setting aside "FDA Letter Decision" under the APA).

a. FDA's Refusal to Accept Letter is "final agency action" because it is a final determination by the agency that Plaintiff's PMTAs are not eligible for filing review. *See Bennett v. Spear*, 520 U.S. 154, 177-78 (1997) (stating a "final agency action" is one that "marks the consummation of the agency's decision-making process" and that is not "tentative or interlocutory in nature") (cleaned up); *see also, e.g.*, 21 C.F.R. § 1114.29(b) (FDA closes a PMTA when it issues a Refuse to Accept Letter).

b. FDA's Refusal to Accept Letter is "final agency action" also because it disqualifies the products at issue from FDA's enforcement discretion policy for ENDS products with timely-filed PMTAs undergoing any stage of FDA review. *See Bennett*, 520 U.S. at 178 (stating a "final

agency action" is "one by which rights or obligations have been determined or from which legal consequences will flow") (cleaned up); *see also* Ex. A, Refuse to Accept Letter at 3 (warning that the marketing of the products at issue "is a prohibited act" that "could result in enforcement action by FDA").

49. FDA's Refusal to Accept Letter for the PMTAs at issue was based solely on the agency's determination that Plaintiff's "FDA Form 4057b … did not include the length [of the] products."[5]

50. FDA's Refusal to Accept Letter was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law because Plaintiff's FDA Forms 4057b did include the lengths of the products at issue.

51. FDA's Refusal to Accept Letter was also arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law because other portions of the PMTAs included the lengths of the products at issue.

[5] Paragraphs 2 and 3 of FDA's Refusal to Accept Letter list additional PMTAs that FDA refused to accept for reasons in addition to the allegedly missing information on length. Those PMTAs are not at issue in this Complaint. The Refusal to Accept Letter also indicates that FDA did not review a July 7, 2022 amendment to the PMTA for various reasons. Ex. A, Refuse to Accept Letter at 2-3, 24. But the amended Forms 4057b were submitted in later amendments, dated October 19, 2022, which FDA did review. *See id.* at 24.

52. FDA's Refusal to Accept Letter injures Plaintiff in that it denies Plaintiff the filing review of its PMTAs to which Plaintiff is entitled under 21 C.F.R. § 1114.27(b).

53. FDA's Refusal to Accept Letter injures Plaintiff in that it disqualifies the products at issue from FDA's enforcement discretion policy for ENDS products with timely-filed PMTAs undergoing any stage of FDA review.

54. The relief Plaintiff requests in this Complaint – a judgment setting aside FDA's Refusal to Accept Letter and ordering FDA to accept Plaintiff's PMTAs for filing review under 21 C.F.R. § 1114.27(b) – would redress Plaintiff's injuries in two ways:

a. It would result in Plaintiff obtaining filing review of its PMTAs; and

b. It would render the products at issue eligible for FDA's enforcement discretion policy for ENDS products with timely-filed PMTAs undergoing any stage of FDA review.

REQUEST FOR RELIEF

55. Plaintiff respectfully requests that this Court enter judgment in its favor that includes the following relief:

a. A declaration pursuant to 28 U.S.C. § 2201 that Plaintiff's PMTAs for the products at issue in this Complaint complied with the content and format requirements for PMTAs and that FDA's Refuse to Accept Letter for those products was arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with the law;

b. An order setting aside and remanding FDA's Refuse to Accept Letter for the PMTAs for the products at issue in this Complaint;

c. An order that FDA accept for filing review Plaintiff's PMTAs for the products at issue in this Complaint;

d. An order awarding Plaintiff its costs, expenses, and fees (including attorney fees) pursuant to 28 U.S.C. § 2412; and

e. An order granting such further relief as is necessary and appropriate.

Dated this 2nd day of August, 2023.

Signature appears on following page.

Respectfully Submitted,

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CERTIFICATE OF COUNSEL REGARDING FONT SIZE

Counsel certifies that the foregoing has been prepared using Times New Roman font size 14 in accordance with Local Rule 5.1(C).

This 2nd day of August, 2023.

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